

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio, v. Purdue Pharma L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

“Track Three Cases”

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS’ MEMORANDUM IN OPPOSITION TO PHARMACY
DEFENDANTS’ MOTION FOR RECONSIDERATION OR
CERTIFICATION**

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INTRODUCTION

Pharmacy Defendants have moved for reconsideration of two elements of this Court's August 6, 2020 Order denying their Motion to Dismiss Plaintiffs' Second Amended Complaints (Doc. 3403): the ruling that Defendants have duties under the Controlled Substances Act (CSA) to maintain effective controls against diversion in dispensing opioids, and the ruling that Ohio Rev. Code § 4729.35 does not preclude Plaintiffs from bringing their public nuisance claim for abatement at common law. Alternatively, Defendants ask the Court to certify the former ruling for interlocutory appeal to the Sixth Circuit and the latter ruling to the Ohio Supreme Court.

Defendants offer no justification for either reconsideration or certification, apart from their disagreement with the Court's decisions. They repeat arguments advanced in support of their motion to dismiss, and cite virtually the same authority. Because Defendants have not met the high threshold for reconsideration or certification and, more importantly, because the Court's rulings were correct, Defendants' motion should be denied.

LEGAL STANDARD

Plaintiffs largely concur with Defendants' summation of the appropriate legal standards applicable to this motion. Reconsideration under Rule 54(b) may be warranted where "there is . . . a need to correct a clear error or prevent manifest injustice." *Louisville/Jefferson Cnty. Metro Gov't v. Hotels.com, L.P.*, 590 F.3d 381, 389 (6th Cir. 2009). This may occur if a motion for reconsideration "calls . . . attention to an argument or controlling authority that was overlooked or disregarded in the original ruling, presents evidence or argument that could not previously have been submitted, or successfully points out a manifest error of fact or law." *Jackson v. City of Cleveland*, 219 F. Supp. 3d 639, 642 (N.D. Ohio 2016) (internal quotation marks omitted).

Under 28 U.S.C. § 1292(b), in order for a district court to certify an order for interlocutory

appeal, three conditions must exist: “(1) the order involves a controlling question of law [as] to which there is (2) substantial ground for difference of opinion and . . . (3) an immediate appeal may materially advance the termination of the litigation.” *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017). As the Sixth Circuit has explained, “[r]eview under § 1292(b) should be sparingly granted and then only in exceptional cases.” *Vitols v. Citizens Banking Co.*, 984 F.2d 168, 170 (6th Cir. 1993); *see also Page Plus of Atlanta, Inc. v. Owl Wireless, LLC*, 733 F.3d 658, 659 (6th Cir. 2013) (finality rule “guards against piecemeal appeals that permit litigants to second-guess the district court at each turn, harming the district court's ability to control the litigation in front of it and consuming finite appellate court resources along the way.”).

Finally, the Ohio Supreme Court may answer a question of state law certified to it by a federal court if the certifying court certifies both that “the question of Ohio law . . . may be determinative of the proceeding” and also that “there is not controlling precedent in the decisions of” the Ohio Supreme Court on that question. Ohio S. Ct. Prac. R. 9.01.

ARGUMENT

I. DEFENDANTS DO NOT DEMONSTRATE ANY BASIS FOR THE COURT TO RECONSIDER ITS RULING THAT THE PHARMACY DEFENDANTS HAVE DUTIES UNDER THE CSA TO PROVIDE EFFECTIVE CONTROLS AGAINST DIVERSION

Defendants pay lip service to the standard for reconsideration, but make no attempt to show any basis for the Court to reconsider its ruling that the Pharmacy Defendants have duties under the CSA to provide effective controls against diversion. Defendants point to no argument or controlling authority that was overlooked or disregarded in the original ruling, and present no evidence or argument that could not previously have been submitted. Moreover, any attempt to suggest that the Court’s ruling involves a “manifest error” is precluded by Defendants’ insistence that the Court’s ruling on this point involves a question

of first impression. *See* Def. Br. at 22. The issue was fully briefed and decided by the Court. Defendants disagree with the Court's ruling, as is their prerogative, but that disagreement provides no basis for the Court to expend judicial resources revisiting an issue just decided.

This is especially true because the Court's decision was correct. Relying on the express language of 21 C.F.R. § 1301.71(a), the Court correctly found that "*all* registrants have an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly." Doc. 3403 at 15 (emphasis in original). "To conclude otherwise," the Court continued, "disregards the plain meaning of the text, undermines the purpose of the CSA, and would allow a frightening abdication of responsibility." *Id.* Defendants point to no flaw in this reasoning, nor could they. The CSA clearly requires all registrants to protect against diversion, and no provision of the statute or regulations limits the Pharmacy Defendants' responsibilities to guarding against diversion through theft alone.

Defendants' attack on the Court's decision rests on a fundamental mischaracterization of the ruling. Contrary to Defendants' argument, the Court did not rule that Defendants must protect against diversion merely because they are required to collect prescription data and keep records. Rather, as the above discussion makes clear, the Court grounded its decision in the plain language of a regulation explicitly requiring them to provide "effective controls" against diversion. The Court used the requirements of data collection and record-keeping as confirmation that the DEA expects pharmacies to assist in preventing diversion and that the duties of the pharmacies are not limited, as Defendants suggest, to guarding against theft. The Court also noted that the record-keeping requirements of the CSA give the Pharmacy Defendants tools for carrying out their obligations to protect against diversion -- tools that it is not unreasonable to expect them actually to use, in light of their over-arching obligations under

the regulatory scheme.

The Court considered what would be necessary to render a pharmacy's controls against diversion "effective" in light of the other obligations placed on pharmacies under the CSA and the information they are required to collect and maintain. Thus, the Court properly construed the scope of § 1301.71 by considering the entire regulatory scheme of which it is a part. Defendants' suggestion that it was somehow improper for the Court to consider these other requirements in construing the scope of the obligation to provide effective controls against diversion should be rejected. *See Keen v. Helson*, 930 F.3d 799, 803 (6th Cir. 2019) ("Statutory interpretation is a 'holistic endeavor' – the structure and wording of other parts of a statute can help clarify the meaning of an isolated term"); *see also Maracich v. Spears*, 570 U.S. 48, 65 (2013) ("It is necessary and required that an interpretation of a phrase of uncertain reach is not confined to a single sentence when the text of the whole statute gives instruction as to its meaning"); *accord Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017) (quoting *Maracich* and noting that construction of a particular section of a statute is not limited to the text of that section in isolation). Indeed, Defendants would no doubt object to a construction of "effective controls" that required them to use information *not* readily available to them; they should not be heard to complain that the Court took into account the information they actually have in construing their obligations.

Defendants also argue that the requirement to maintain effective controls does not encompass a corporate duty to identify and clear "red-flags" indicative of diversion. But, as Plaintiffs previously demonstrated, the DEA has construed the CSA and its regulations to include the requirement that pharmacies not fill prescriptions until "red flags" indicative of diversion have been resolved. *See, e.g., Medicine Shoppe-Jonesborough v. Drug Enforcement*

Administration, 300 F. App'x 409 (6th Cir. 2008); *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044, 1990 WL 328750 (Dep't of Justice July 24, 1990) ("a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose."); *East Main Street Pharmacy; Affirmance of Suspension Order*, 75 FR 66149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010) ("[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions."); *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730, 1990 WL 352775 (Dep't of Justice Feb. 9, 1990); *Townwood Pharmacy*; 63 Fed. Reg. 8,477, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998); *Grider Drug 1 & Grider Drug 2*; 77 FR 44070-01, 2012 WL 3027634 (Dep't of Justice July 26, 2012); *The Medicine Dropper*; 76 Fed. Reg. 20,039, 2011 WL 1343276 (Dep't of Justice April 11, 2011); *Medicine Shoppe-Jonesborough*; 73 FR 364-01, 2008 WL 34619 (Dep't of Justice Jan. 2, 2008). Courts and the DEA have further rejected the argument Defendants make that this obligation applies only to individual pharmacists and does not reach pharmacies and corporate entities. *See Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189 (E.D. Ky. Mar. 30, 2017); *United Prescription Services, Inc. Revocation of Registration*, 72 FR 50397-01 (DEA Aug. 31, 2007); *see also* Doc. 3366 at 17 n.20.¹

¹ The recent decision of a Magistrate Judge in *United States v. McKesson Corp.*, No. 19-CV-02233-DMR, 2020 WL 4805034 (N.D. Cal. Aug. 18, 2020), cited by Defendants, does not support their argument. The issue in *United States v. McKesson* was whether a wholesale distributor's invoices contained an implicit false representation, for purposes of the False Claims Act ("FCA"), that the security measures at the defendant's distribution centers complied with the CSA. The Magistrate Judge found that the security requirements of the CSA for distribution centers were insufficiently precise to support a claim under the FCA -- that is, even if the defendant's security measures in fact failed to comply with the CSA, it could not be found liable for falsely representing that it was in compliance. 2020 WL 4805034, **4-5. The case has nothing to do with the scope of the Pharmacy Defendants' duty to maintain effective controls

Defendants dispute that DEA has required corporate entities to use information in their possession to maintain effective controls, but their argument amounts only to the assertion that DEA has not addressed the precise facts at issue here. Their attempt to distinguish Plaintiffs' cases, *yet again*, provides no basis for reconsideration.

Nor, in any case, are Defendants correct. As noted above, DEA has repeatedly held that individual pharmacists may not ignore information in their possession indicative of diversion when they fill narcotic prescriptions and has imposed responsibility on corporate entities. Defendants' position is that, unlike individuals, corporate pharmacy entities should be permitted to ignore the information in their possession, which is vastly more sophisticated and extensive. In essence, they argue that a corporate entity, unlike an individual, is permitted to be willfully blind and ignore what it knows. But the DEA has never carved out a corporate *exception* to the prohibition on willful blindness in the filling of opioid prescriptions.

Indeed, CVS itself recognized in 2013 that because individual pharmacists "have access to very little other background information" beyond the face of a prescription, it is "difficult for individual pharmacists to use their own partially informed judgment to identify prescriptions that have come from a pill-mill doctor." See Betses, M., *Abusive Prescribing of Controlled Substances – A Pharmacy View*, N. ENGL. J. MED. 369:11 (Sept. 12, 2013). By contrast, CVS explained, chain pharmacies "have the advantage of aggregated information on all prescriptions filled at the chain." *Id.* They are able to use this information to identify illegitimate prescribing patterns not readily apparent on the basis of an individual prescription.

against diversion or whether these Defendants may be found liable for creating a public nuisance.

Id. This perfectly describes the difference between information available to an individual and information available to entities such as the Pharmacy Defendants. Yet, Defendants ask the Court to pretend this is not so.

The Court's recognition that systematic analysis of the data in a pharmacy chain's possession may be required to provide effective controls against diversion is nothing more than the application, to corporate entities with vast quantities of data, of the same requirement DEA has repeatedly imposed on individuals – to understand and use what they know. The Pharmacy Defendants' insistence that corporate knowledge be treated as nothing more than the aggregation of individual knowledge is a recipe for the willful dispersion of information in the service of avoiding responsibility.

Nor do the DEA decisions Defendants cite support their crabbed reading. Even if a "red flag" prescription must be recognizable when it is presented, the circumstances that make it recognizable can surely include information in the company's knowledge about prior prescriptions. The Pharmacy Defendants' choice not to analyze and provide this information to their pharmacists so as to impede the pharmacists' ability to recognize "red flags" does not insulate these Defendants from liability. Pharmacy Defendants' gloss – that a "red flag" must be recognizable *to a human* – is unsupported by DEA precedent and does not in any event support their position. For what is recognizable to a human surely includes what a human can recognize with the assistance of a computer database. Defendants ask this Court to pretend that their pharmacists are filling prescriptions in the 1930's, even as Defendants themselves use 21st century technologies to collect and analyze data to assist them in maximizing their profits.

Finally, this Court can and should reject Defendants' new contention that requiring them to maintain effective controls against diversion may expose them to liability for refusing

to fill lawful prescriptions. Defendants well know that they cannot be held liable under state law for carrying out duties mandated by federal law. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 566-73 (2009). Moreover, Congress, and the DEA, made the decision to include “effective controls against diversion” as a critical element in the regulatory structure for dangerous but therapeutically-useful substances such as opioids, which, despite their therapeutic value, have a high potential for abuse and diversion. The Pharmacy Defendants cannot escape their responsibilities under the CSA to control the flow of these drugs merely because some patients, even legitimate pain patients, may not appreciate the importance of preventing diversion. (This is especially true because patients in severe pain may, in appropriate circumstances, receive medication directly from a treating physician in a hospital or doctor’s office, ensuring that such patients are not without recourse.)

It was not manifestly erroneous for the Court to find that, just like the individual pharmacists they employ, the Pharmacy Defendants are not free to ignore the information in their possession, and indeed to conclude that the Defendants’ alternative construction would permit a “frightening abdication of responsibility.” Doc. 3403 at 15.² Defendants have

² Defendants attempt to sidestep this concern by mischaracterizing Plaintiffs’ claims as concerning only “whether facially valid prescriptions written by authorized prescribers should have been filled.” *See* Def. Br. at 14. This is, of course, not the case. Plaintiffs have alleged that the Pharmacy Defendants were responsible for the diversion of opioids in Plaintiffs’ communities because these Defendants failed to implement “effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market.” [*Lake Amended Complaint*] at ¶ 83; *see also id.* at ¶¶ 139-155. Plaintiffs have also alleged that the Pharmacy Defendants failed to detect obvious indicia of diversion. *Id.* Indeed, Defendants’ argument merely underscores the Court’s concerns about the abdication of responsibility: if a prescription is “facially valid,” but a pharmacy chain is in possession of information demonstrating that the prescription likely is *invalid* and an instrument of diversion, how can the refusal to investigate before handing over dangerous addictive narcotics be characterized as anything other than a total abdication of responsibility?

provided no basis for the Court to reconsider this ruling.

II. DEFENDANTS DO NOT DEMONSTRATE ANY BASIS FOR THE COURT TO RECONSIDER ITS RULING THAT PLAINTIFFS' NUISANCE CLAIMS ARE NOT PRECLUDED BY OHIO REV. CODE § 4729.35

The Pharmacy Defendants' second argument for reconsideration, regarding the proper rule of statutory construction under Ohio law, should likewise be denied.

First, Defendants merely repeat the arguments from their reply brief in support of their motion to dismiss regarding the proper rule of statutory construction³—arguments which the Court has already considered and squarely rejected.⁴ Thus, Defendants have not provided a proper basis for the Court to reconsider its ruling.

Second, as the Court has already concluded, Defendants are simply wrong about the proper rule of statutory construction. For over 125 years, the Ohio Supreme Court has consistently and repeatedly declared that the common law will not be abrogated by statute unless the statute clearly expresses or imports such an intention.⁵ In 2018, the Bankruptcy

³ See Defendants' Reply Brief (Doc. 3379) at 2 ("The 'rule of statutory construction' [Plaintiffs] invoke, Opp. 5-6, applies only to the repeal of 'settled rules of common law' when the statute in question is tangential to the rule of common law.") (citing *State ex rel. Morris v. Sullivan*, 90 N.E. 146, para. 3 of syllabus (Ohio 1909)).

⁴ See Opinion and Order (Doc. 3403) at 6-7 ("Defendants' theory, however, constrains the *Morris* rule of construction to an unsupportable level of specificity. Defendants ignore that Ohio courts for many decades have recognized a common law claim for absolute public nuisance based on a defendant's unlawful conduct. Undoubtedly, the General Assembly was aware of the *Morris* rule of construction when it enacted § 4729.35 and could easily have abrogated some or all of the existing species of common law public nuisance claims[.]").

⁵ See e.g., *Combs v. Ohio Dep't of Nat. Res., Div. of Parks & Recreation*, 55 N.E.3d 1073 ¶ 18 (Ohio 2016) (quoting *Vaccariello, infra*); *Mann v. Northgate Inv'rs, L.L.C.*, 5 N.E.3d 594, ¶ 17 (Ohio 2014) ("[S]tatutes are presumed to embrace the common law extant at their enactment."); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002) ("The learned intermediary doctrine is codified at R.C. 2307.76(C). The codification does not thereby abrogate the common law. In *Carrel*, we stated that 'in the absence of language clearly showing the intention to

Appellate Panel of the Sixth Circuit reiterated the rule: “A court construing a statute should not presume that a legislature intended to repeal settled rules of common law unless the statutory language clearly expresses or imports such intention.” *In re Nicole Gas Prod., Ltd.*, 581 B.R. 843, 850 (B.A.P. 6th Cir. 2018) (quoting *Mann v. Northgate Investors, L.L.C.*, 5 N.E.3d 594, 598–99 (Ohio 2014)).

In the face of this extensive support for the Court’s conclusion, Defendants cannot point to a single case that holds that the *Morris* rule only applies in cases in which the statute is

supersede the common law, the existing common law is not affected by the statute, but continues in full force.”) (quoting *Carrel*); *Carrel v. Allied Products Corp.*, 677 N.E.2d 795, 798 (Ohio 1997) (“The court of appeals found that the General Assembly, by codifying products liability law, had abrogated the common-law negligent design claim. . . . The court concluded that the statutes’ silence meant that the General Assembly had chosen to eliminate this type of action against a manufacturer. . . . We find these assertions and conclusions contrary to well-established rules of statutory construction[.] . . . According to principles of statutory construction, the General Assembly will not be presumed to have intended to abrogate a common-law rule unless the language used in the statute clearly shows that intent.”) (citing *Morris*); *Shump v. First Continental-Robinwood Assoc.*, 644 N.E.2d 291, 297 (Ohio 1994) (quoting *Morris*); *Bresnik v. Beulah Park Ltd. Partnership, Inc.*, 617 N.E.2d 1096, 1098 (Ohio 1993) (quoting *Morris*); *Smith v. Mitchell*, 520 N.E.2d 213, 214–15 (Ohio 1988) (quoting *Morris*); *LaCourse v. Fleitz*, 503 N.E.2d 159, 162 (Ohio 1986) (“Courts may not presume that the statute was intended to abrogate the common law. Such an intention must be expressly declared by the legislature or necessarily implied in the language of the statute.”) (citing *Branham v. Fordyce*, 145 N.E.2d 471, 474 (Ohio Ct. App. 1957); *State v. Phillips*, 97 N.E. 976, 977 (Ohio 1912) (“Common-law rules have usually been founded upon sound reason and considerations of public policy, and out of this fact has grown the safe maxim that statutes derogating from the common law should be strictly construed. Keeping this maxim in mind, we have found nothing in the statutes of Ohio, and nothing has been pointed out to us, which would justify a conclusion that the General Assembly expressly or impliedly abrogated the common-law rule[.]”); *State ex rel. Morris v. Sullivan*, 90 N.E. 146, syllabus ¶ 3 (Ohio 1909) (“Statutes are to be read and construed in the light of and with reference to the rules and principles of the common law in force at the time of their enactment, and in giving construction to a statute the Legislature will not be presumed or held to have intended a repeal of the settled rules of the common law, unless the language employed by it clearly expresses or imports such intention.”); *Krause v. Morgan*, 53 Ohio St. 26, 42, 40 N.E. 886, 890 (Ohio 1895) (“The legislature will not be held to intend a repeal of the settled rules of the common law, unless the language employed by it clearly imports such an intention.”) (quotations and citations omitted).

“tangential” to the common law. Indeed, the principal authority on which Defendants rely is a *dissenting* opinion in *Carrel*, an opinion that was *expressly rejected* by the majority in the course of applying the *Morris* rule over the dissent’s objection. *Carrel*, 677 N.E.2d at 798-99.⁶ Moreover, the rule advocated by Defendants would be totally unworkable in practice. Nor have Defendants “demonstrated [that] § 4729.35 is a codification of common law.” Order (Doc. 3403) at 11.

Thus, the Court correctly held that R.C. § 4729.35 does not abrogate Plaintiffs’ common law public nuisance causes of action, and the Court should not reconsider its ruling.

III. NEITHER INTERLOCUTORY APPEAL NOR CERTIFICATION IS APPROPRIATE HERE

Nor should this Court entertain the alternative form of relief sought by Defendants. The two rulings challenged by Defendants satisfy neither the requirements for interlocutory appeal under 28 U.S.C. § 1292(b), nor the requirements for certifying a question of state law to the Ohio Supreme Court.

A. The Court’s Construction of Defendants’ CSA Duties Does Not Meet the Requirements for Interlocutory Appeal under § 1292(b)

Section 1292(b) permits the Court to certify its ruling for interlocutory appeal when the Court is of the opinion that the ruling “involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation.” 28 U.S.C.A. § 1292. The

⁶ In addition to the dissenting opinion in *Carrel*, Defendants point to dicta in a footnote in *Miles v. Raymond Corp.*, 612 F.Supp.2d 913 (N.D. Ohio 2009), in which the court referenced the dissent in *Carrel*, but clearly stated “this potential distinction need not be addressed.” *Id.* at 921, n. 6. The other cases Defendants cite (*Ohioans for Concealed Carry v. City of Columbus*, 140 N.E.3d 1215 (Ohio Ct. App. 2019); *Mann v. Northgate*, 5 N.E.3d 594 (Ohio 2014); *Smith v. Mitchell*, 520 N.E.2d 213 (Ohio 1988); and *Seasongood v. Seasongood*, 27 Ohio C.D. 200 (Ohio Ct. App. 1915)) are examples of courts *applying* the *Morris* rule, but none of those cases even suggest that the *Morris* rule is limited to cases in which the statute is “tangential” to the common law.

Court's ruling concerning the Pharmacy Defendants' CSA duties satisfies none of these criteria and does not warrant immediate appeal.

First, the ruling that the Pharmacy Defendants have duties under the CSA to provide effective controls against diversion (including the duty to make use of the information in their possession) is not a controlling question of law. Plaintiffs' nuisance claim may be grounded in either unlawful *or* intentional conduct. *See* Doc. 3403 at 26-27; *see also Cincinnati v. Beretta U.S.A.*, 768 N.E.2d 1136, 1141-44 (Ohio 2002); *City of Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *3 -*4 (Ohio Ct. App. March 21, 2013). Even if Defendants were correct that they did not have duties under the CSA that they could have violated – and they are not – Plaintiffs' nuisance claim would still proceed on the basis that Defendants acted intentionally. *See* Doc. 3403 at 27 (“Plaintiffs clearly allege that Defendants engaged in intentional conduct”); *see also Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859 at 863 (N.D. Ohio 2017) (in the context of public nuisance, “intentional . . . means not that a wrong or the existence of a nuisance was intended but that the creator of it intended to bring about the conditions which are in fact found to be a nuisance”).

Second, the question is not one where there is substantial ground for difference of opinion. District courts in this circuit have interpreted this factor to mean that

(1) the question is difficult, novel and either a question on which there is little precedent or one whose correct resolution is not substantially guided by previous decisions; (2) the question is difficult and of first impression; (3) a difference of opinion exists within the controlling circuit; or (4) the circuits are split on the question.

See In re Miedzianowski, 735 F.3d 383, 384 (6th Cir. 2013). Here, as noted above, the text of § 1301.71(a), as well as a wealth of precedent supports the Court's conclusion that dispensers – including corporate pharmacy owners – must provide effective controls against diversion

and may not ignore what they know to be red flags indicative of diversion. As the Court explained in its Order, this precedent is further supported by the purpose of the CSA, the structure of the regulatory scheme, and practical considerations pertaining to the operations of pharmacies. *See* Doc. 3403 at 15 (noting that Defendants' reading of the CSA "disregards the plain meaning of the text, undermines the purpose of the CSA, and would allow a frightening abdication of responsibility"); *id.* at 17 ("It would undermine the entire purpose of the CSA (and defy logic) for the Act to require a pharmacy to collect the dispensing data listed in § 1304.22(c), but then allow the pharmacy to ignore this data when fulfilling its fundamental obligation to guard against diversion"); *id.* at 20-21 (concluding that Ohio law "cannot be read to mean that pharmacy owners *who are not themselves pharmacists* are absolved of responsibility for their own dispensing practices) (emphasis in original); *id.* at 25 ("Possessing, yet doing nothing with, information about possible diversion would *facilitate* diversion") (emphasis in original).

Finally, and relatedly, immediate appeal would not materially advance the ultimate termination of the litigation. Because Plaintiffs' nuisance claims will proceed in any event, immediate appeal of the CSA issue will not obviate the need for discovery, for dispositive rulings, and/or for a trial of Plaintiffs' nuisance claims. Moreover, despite the posture of the ruling – denying a motion to dismiss – this case is not in its infancy; rather, time and effort have already been expended and substantial discovery has already been had. Thus, the relative amount of time by which the case could conceivably be shortened by an interlocutory appeal (if any) is greatly reduced. *See Kelley v. Apria Healthcare, LLC*, 232 F. Supp. 3d 983, 1005 (E.D. Tenn. 2017) ("Interlocutory appeal is most appropriate early in the proceedings. By contrast, the role of interlocutory appeal is diminished when a case is nearing trial and large

expenditures have already been made.”).

Because *none* of the § 1292(b) factors are met, interlocutory appeal is not appropriate here.

B. This Court’s Construction of Ohio Rev. Code § 4729.35 Does Not Meet the Requirements for Certification to the Ohio Supreme Court

Similarly, there is no basis for certifying the Court’s statutory construction ruling to the Ohio Supreme Court. Certification is only appropriate when “there is no controlling precedent in the decisions of this Supreme Court.” Ohio S.Ct.Prac.R. 9.1(A). As stated above, there is an unbroken, 125-year-long line of controlling precedent from the Ohio Supreme Court, as well as a recent Sixth Circuit opinion, reiterating the long-standing rule of statutory construction to be applied in this case. “Certification ‘is most appropriate when the question is new and state law is unsettled. . . . When we see a reasonably clear and principled course, we will seek to follow it ourselves.” *Pennington v. State Farm Mut. Auto. Ins. Co.*, 553 F.3d 447, 450 (6th Cir.2009).

Equally important, the Pharmacy Defendants’ request for certification is untimely: “The appropriate time to seek certification of a state-law issue is *before a District Court resolves the issue, not after receiving an unfavorable ruling.*” *City of Columbus, Ohio v. Hotels.com, L.P.*, 693 F.3d 642, 654 (6th Cir.2012) (emphasis added).

The view that state-law issue certification should be sought before, not after, a district court resolves the issue, is shared by many of our sister circuits. *See, e.g., Thompson v. Paul*, 547 F.3d 1055, 1065 (9th Cir.2008) (“There is a presumption against certifying a question to a state supreme court after a federal district court has issued a decision.”); *Enfield v. A.B. Chance Co.*, 228 F.3d 1245, 1255 (10th Cir.2000) (denying certification where party did not seek certification until adverse decision and stating “[t]hat fact alone persuades us that certification is inappropriate”); *Perkins v. Clark Equip. Co., Melrose Div.*, 823 F.2d 207, 209–210 (8th Cir.1987) (discouraging requests for certification made by a party after summary judgment has been decided against that party because “[o]therwise, the initial federal court decision will be nothing but a gamble with certification sought only after an adverse decision”).

Id. Defendants improperly seek a second bite at the apple now that this Court has ruled against them.

Defendants do not meet the legal standard for certification to the Ohio Supreme Court. The question of law at issue is not new or unsettled, and Defendants waited until after they received an unfavorable ruling to seek certification.⁷ Defendants request for certification should thus be denied.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion for reconsideration in its entirety and should decline to certify its decision either for interlocutory appeal to the Sixth Circuit or on certified question to the Ohio Supreme Court.

Dated: September 8, 2020

Respectfully submitted,

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⁷ Defendants made passing reference to certification in their Reply brief (Doc. 3379) in footnote 3, but only stated certification would be appropriate "[t]o the extent the Court finds Ohio law unsettled as to which rule of construction should apply to § 4729.35[.]" The Court did not find the law unsettled and ruled against Defendants. Now Defendants seek certification after receiving the unfavorable ruling.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 8th day of September, 2020, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System.

/s/Peter H. Weinberger
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